AMENDMENT TO MR. TAUZIN'S AMENDMENT

OFFERED BY M.

(Page & line nos. refer to Chairman's Mark of June 17, 2003)

Amend section 621(c) (page 214, line 12, through page 215, line 3) to read as follows:

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

''(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

''(i) IN GENERAL.—The Secretary may not apply a 'functional equivalence' or similar standard to a drug or biological under this paragraph.

''(ii) LIMITED APPLICATION.—Clause (i) shall apply to the application of a 'functional equivalent' or similar standard to a drug or biological on or after the date of the enactment of this subparagraph, unless—

''(I) such application was being made to such drug or biological before such date; and

''(II) the Secretary applies, or has applied, such 'functional equivalent' or similar standard to such drug or biological only for the purpose of determining the eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

''(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as affecting the Secretary's authority to deem a particular drug or biological to be identical to another drug or biological if the two drugs or biologicals are pharma-

ceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.''.